

APPENDIX B



Atty. Dkt. No. 053466-0296

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Tadimitsu KISHIMOTO, *et al.*

Title: CHRONIC RHEUMATOID ARTHRITIS THERAPY
CONTAINING IL-6 ANTAGONIST AS EFFECTIVE
COMPONENT

Appl. No.: 09/756,125

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DECLARATION OF YUKO GIRDWOOD.
PURSUANT TO 37 C.F.R. § 1.132

Mail Stop NON-FEE AMENDMENT
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

I, Yuko Girdwood, declare as follows:

1. I was born and raised in Japan, am a Japanese Citizen, and am fluent in spoken and written Japanese.
2. I have been a resident in the United States for seventeen (17) years. I am fluent in spoken and written English.
3. I have been employed as a paralegal by Foley and Lardner LLP for seven and half (7.5) years. I have no financial or other interest in the invention, nor have I been paid for this particular opinion other than my regular salary. Moreover, I will retire on November 30, 2007, (tomorrow) and so my opinion is not influenced by future employment with Foley and Lardner LLP.

4. In my capacity as a translator, I have been asked to opine on possible translations of Japanese text appearing in WO 96/11020:

5. Page 7, lines 1-11 in WO 96/11020 read:

このような抗体は、IL-6抗体としては、MH166 (Matsudaら、Eur. J. Immunol. 18:951-956, 1988) やSK2抗体 (Satoら、第21回日本免疫学会総会、学術記録、21:116, 1991) 等が挙げられる。IL-6R抗体としては、PM-1抗体 (Hirataら、J. Immunol. 143:2900-2906, 1989)、AUK12-20抗体、AUK64-7抗体あるいはAUK146-15抗体 (国際特許出願公開番号WO 92-19759) などが挙げられる。gp130抗体としては、AM64抗体 (特開平3-219894) が挙げられる。

これらのうちでも特に、PM-1抗体が好ましい。

6. As Japanese does not distinguish between singular and plural forms in same way as English and the original Japanese-language text (above) does not distinguish between the singular/species and plural/generic forms, a translation to either singular or plural forms in English is correct. Therefore, the above text can be translated into

Examples of antibodies which are IL-6 antibodies include MH166 antibodies (Matsuda et al., Eur. J. Immunol. 18:951-956, 1988) and SK2 antibodies (Sato et al., Journal for the 21st General Meeting of the Japan Immunology Association, 21:116, 1991). Examples of IL-6R antibodies include the PM-1 antibodies (Hirata et al., J. Immunol. 143:2900-2906, 1989), AUK12-20 antibodies, AUK64-7 antibodies and AUK146-15 antibodies (Intl. Unexamined Patent Application No. WO 92-19759). Examples of gp130 antibodies are AM64 antibodies (Japanese Unexamined Patent Publication No. 3-219894).

Among these, PM-1 antibodies are particularly preferred.

7. Page 11, lines 12-18 of WO 96/11020 read:

さらに、再構成（reshaped）したヒト抗体を本発明に用いることができる。これはヒト以外の哺乳動物、たとえばマウス抗体の相補性決定領域をヒト抗体の相補性決定領域へ置換したものであり、その一般的な遺伝子組換手法も知られている。その既知方法を用いて、本発明に有用な再構成ヒト型抗体を得ることができる。例えば、このような再構成ヒト抗体として、hPM-1が好ましい（国際特許出願公開番号WO 92-19759を参照）。

8. As Japanese does not distinguish between singular and plural forms in same way as English and the original Japanese-language text (above) does not distinguish between the singular/species and plural/generic forms, a translation to either singular or plural forms in English is correct. Thus, the above text can be translated into:

Reshaped human antibodies may also be used according to the invention. These are prepared by using the complementary determinant region of a mouse or other non-human mammalian animal antibody to replace the complementary determinant region of a human antibody, and conventional gene recombination methods therefor are well-known. One of the known methods may be used to obtain a reshaped human antibody which is useful according to the invention. Preferred examples of such reshaped human antibodies are hPM-1 (see Intl. Unexamined Patent Application No. WO 92-19759).

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: November 29, 2007


Yuko Girdwood